

INFORMATION DISCLOSURE STATEMENT


Applicant : Gadde, et al.
App. No : 10/830,071
Filed : April 23, 2004
For : METHOD FOR TREATING OBESITY
Examiner : Jones, Dwayne C.
Art Unit : 1614

CERTIFICATE OF MAILING

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October 17, 2006

(Date)


Joseph J. Mallon, Reg. No. 39,287

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 137 references to be considered by the Examiner. Also enclosed are 91 foreign patent references and/or non-patent literature as listed on the Information Disclosure Statement.

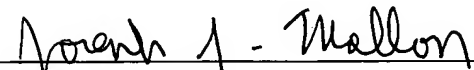
This Information Disclosure Statement is being filed within three months of the filing date, with an RCE or before receipt of a first office action after an RCE and no fee is required.

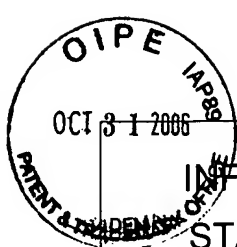
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 17 October 2006

By: 
Joseph J. Mallon
Registration No. 39,287
Attorney of Record
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Multiple sheets used when necessary)

SHEET 1 OF 7

Application No.	10/830,071
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Examiner	Jones, Dwayne C.
Attorney Docket No.	OREX.009C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	3,819,706	06-25-1974	Mehta, N.	
	2	3,885,046	05-20-1975	Mehta, N.	
	3	4,089,855	05-16-1978	Chatterjie et al.	
	4	4,673,679	06-16-1987	Aungst et al.	
	5	4,689,332	08-25-1987	McLaughin et al.	
	6	5,358,970	10-25-1994	Ruff, et al.	
	7	5,426,112	06-20-1995	Zagon, et al.	
	8	5,427,798	06-27-1995	Ludwig, et al.	
	9	5,512,593	04-30-1996	Dante	
	10	5,541,231	07-30-1996	Ruff, et al.	
	11	5,719,197	02-17-1998	Kanios et al.	
	12	5,731,000	03-24-1998	Ruff, et al.	
	13	5,763,493	06-09-1998	Ruff, et al.	
	14	5,817,665	10-06-1998	Dante	
	15	5,856,332	01-05-1999	Dante	
	16	5,958,962	09-28-1999	Dante	
	17	6,004,970	12-21-1999	O'Malley, et al.	
	18	6,034,091	03-07-2000	Dante	
	19	6,071,918	06-06-2000	Cook	
	20	6,110,973	08-29-2000	Young, James	
	21	6,262,049	07-17-2001	Coffin et al.	
	22	6,344,474	02-05-2002	Maruani et al.	
	23	6,441,038	08-27-2002	Cook	
	24	6,541,478	04-01-2003	O'Malley, et al.	
	25	6,569,449	05-27-2003	Stinchcomb et al.	
	26	5,713,488	03-30-2004	Sadee, et al.	
	27	2003-0144174	07-31-2003	Brenna et al.	
	28	2003-0055008	03-20-2003	Marcotte, David B.	
	29	2004-0002462	01-01-2004	Najarian	

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	30	2004-0033965	02-19-2004	Gadde, et al.	
	31	2004-0106576	06-03-2004	Jerussi, et al.	
	32	2004-0122033	06-24-2004	Nargund, et al.	
	33	2004-0254208	12-16-2004	Weber et al.	
	34	2005-0026986	02-05-2003	Maruani et al.	
	35	2005-0137144	06-23-2005	Gadde, et al.	
	36	2005-0143322	06-30-2005	Gadde, et al.	
	37	2005-0154002	07-14-2005	Crooks, et al.	
	38	2005-0181070	08-18-2005	Gadde et al.	
	39	2005-0215552	09-29-2005	Gadde et al.	
	40	2005-0277579	12-15-2005	Krishnano, et al.	
	41	2006-0009514	01-12-2006	Gadde et al.	
	42	2006-0058293	03-16-2006	Weber, et al.	
	43	2006-0079501	04-13-2006	Gadde et al.	
	44	2006-0100205	05-11-2006	Weber, et al.	
	45	2006-0142290	06-29-2006	Weber, et al.	
	46	2006-0160750	07-20-2006	Gadde et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
	47	WO 00/76493	12-21-2000	Najarian		
	48	WO 03/013524	02-20-2003	Glober Hillel		
	49	WO 03/097046	11-17-2003	Gadde, et al.		
	50	WO 04/009015	01-29-2004	Merck & Co.		
	51	WO 04/096201	11-11-2004	Weber et al.		
	52	WO 05/049043	06-02-2005	Ortho-McNeil		
	53	WO 96/09047	03-28-1996	Du Pont Merck Pharma		
	54	EP 0 442 769 A2	08-21-1991	Guillaument		

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	55	"A Novel Twist on Binge Eating Treatment" Primary Psychiatry; 6(10) 24-29 (1999)	
	56	ANDERSON, et al. Bupropion SR enhances weight loss" Obesity R., Vol. 10, N. 7, 2002, pp. 633-641, XP002351373	
	57	Altman and Bland. "Standard Deviations and Standard Errors," BMJ; 2005:331:903.	
	58	Appolinario et al. "Pharmacological Approaches in the Treatment of Binge Eating Disorder." Current Drug Targets; 5:301-307 (2004).	
	59	Asconape. "Some Common Issues in the Use of Antiepileptic Drugs." Seminars in Neurology; 22(1):27-39 (2002).	
	60	ATKINSON, "Clinical Guidelines on the identification, Evaluation, and pharmacologic treatment of obesity in Adults, Online, 07-25-2003, URL: http://www.endotext.org.obesity/obesity15b/obesity15b.htm .	
	61	BEELEN, et al. "Asymptomatic QTC prolongation associated with quetiapine fumarate overdose in a patient being treated with risperidone" Human & Experimental Toxicology 92001) 20, 215-219.	
	62	CALABRESE, et al. Letters to the Editors, "Lamotrigine and Clozapine for Bipolar Disorder" American J. of Psychiatry, vol. 157 9, September 2000, 1523	
	63	CARLSEN, et al. "Evidence for dissociation of insulin-and weight-reducing effects of metformin in non-diabetic male patients with coronary heart disease" Diabetes Research and Clinical Practice Amsterdam, vol. 39, No. 1, Jan. 1998, pp. 47-54.	
	64	CARROLL, F.I. J. Med. Chem , 46:10 (2003)	
	65	CHEN, et al. "Synergistic Effects of Cannabinoid inverse agonist AM251 and opioid antagonist nalfene on food intake" Brain Res. Vol. 999, January 2004, pp. 22-230	
	66	CHENGAPPA, et al. "Changes in body Weight and Body mass index among psychiatric patients receiving lithium, valproate, or topiramate: an open-label, nonrandomized chart review" Clinical Therapeutics, 24 (10) 1576-1584	
	67	CONE, et al. "The arcuate nucleus as a conduit for diverse signals relevant to energy homeostasis," Int'l Journal of Obesity, 25(5):S63-S67 (2001).	
	68	DECHANT et al. Drugs, 41:225-253 (1991).	
	69	DEMBOWSKI, et al. "Successful Antimanic Treatment and Mood Stabilization with Lamotrigine, Clozapine, and Valproate in a Bipolar Patient after Lithium-induced Cerebellar Deterioration" Letter Pharmacopsychiatry, 2003; 36 83-86.	
	70	DEVLIN, et al. "Int. J. Eating Disord. 28:325-332 (2000)	
	71	Diagnostic and Statistical Manual of Mental Disorders. 4th Edition, Text Revision, p.583-595 (2000).	
	72	DURSEN, et al., "Clozapine Plus Lamotrigine in Treatment-Resistant Schizophrenia, Arch Gen Psychiatry Vol. 56, Oct. 1999, 950-951.	

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	73	DURSUN, et al. "Lamotrigine-Clozapine Combination in Refractory Schizophrenia: Three Cases" J. Neuropsychiatry Clin. Neuroscience, 14:1, Winter 2002, 86	
	74	DURSUN, et al. "Augmenting Antipsychotic treatment with Lamotrigine or topiramate in patients with treatment-resistant Schizophrenia: a naturalistic case-series outcome study" Journal of Psychopharmacology 15(4) 2001- 297-301.	
	75	DURSUN, et al., "Psychopharmacology for the Clinician Psychopharmacologie Pratique" Journal of Psychiatry Neuroscience, vol. 26 No. 2, 2001, 168	
	76	DURSUN, et al. "Accelerated Weight Loss After Treating Refractory Depression with Fluoxetine Puls Topiramate: Possible Mechanism of Action" Canadian Journal of Psychiatry, vol. 46, No. 3 April, 2001, pp. 287-288	
	77	EREZ et al. J. Med. Chem., 25:847-849 (1982).	
	78	Faught et al. "Randomized Controlled Trial of Zonisamide for the Treatment of Refractory Partial-Onset Seizures." Neurology; 57(10):1774-1779 (2001).	
	79	FINGL et al. The Pharmacological Basis of Therapeutics. Ch.1, pp 1. (1975).	
	80	FULLER et al., Fluoxetine: A Serotonergic Appetite Suppressant Drug, Drug Development Research, Vol. 17, No. 1, 1989, pages 1-15; XP009035038	
	81	Gadde et al. Inpharma; 1383(84):9 (2003).	
	82	GATLEY, et al. "European Journal of Pharmacology, 307:331-338 (1996)	
	83	GLASS et al. Neuropeptides, 33:360-368 (1999)	
	84	GORDON, et al. "Mood Stabilization and Weight Loss with Topiramate" American Journal of Psychiatry, American Psychiatric Association, Washington D.C. Vol. 156, No. 6, June 1999, pp. 968-969	
	85	HAHN, et al. J. Pharm Exper. Therapeutics 235:846-850.	
	86	Harrison's Principles of Internal Medicine. Eleventh Edition, McGraw-Hill Book Company, p1921-1930 (1987).	
	87	HUSSEY et al. J. Am. Chem. Soc., 125:3692-3693 (2003).	
	88	ISLAM, et al. Naltrexone, Serotonin Receptor Subtype Antagonists, and Carbohydrate Intake in Rats, Pharmacology Biochemistry and Behavior, Vol. 48, No. 1, 1994, pages 193-201; XP002292383	
	89	Jallon et al. Drug Safety; 24(13):969-978 (2004).	
	90	KIPTOO, et al. "Enhancement of Transdermal delivery of 6-B-naltrexol via a codrug linked to hydroxybutyrate, Journal of Controlled Release 113 (2006) 137-145	

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	91	KIRKHAM et al. "Psychopharmacology 153:267-270(2001)	
	92	KOLB et al. A. Pharmaceutical Res., 6:266-271 (1985)	
	93	KLOK et al. Macromolecules, 35:746-759 (2002).	
	94	KORNER et al. "The emerging science of body weight regulation and its impact on obesity treatment," J. Clin. Invest., 111(5):565-570 (2003).	
	95	LE BOURDONNEC et al. J. Med. Chem., 43:2489-2492 (2000).	
	96	Leppik et al. Epilepsy Research; 14:165-173 (1993).	
	97	LESSIG, et al., "Topiramate for Reversing Atypical Antipsychotic Weight Gain" J. Am. Child Adolesc. Psychiatry 40;12 December 2001. p 1364.	
	98	LEVY, et al., "Topiramate Produced Weight Loss Following Olanzapine-Induced Weight Gain in Schizophrenia" J. Clin. Psychiatry 63;11 November 2002, 1045.	
	99	McElroy et al. "Zonisamide in the Treatment of Binge-Eating Disorder: An Open-Label, Prospective Trial." J. Clin. Psychiatry; 65(1):50-56 (2004).	
	100	McElroy et al. Inpharma; 1428:10 (2004)	
	101	MCLAUGHIN, et al, " Behavioral Pharmacology, 14:583:588 (2003)	
	102	NAVARRO, et al. "Topiramate for Clozapine-Induced Seizures" Am. J. Psychiatry 158; 6, June 2001, 968-969	
	103	NDA20-789, ZONEGRAN (zonisamide) Capsules 100 mg, FDA Approved Labeling Text, p1-24 (March 27, 2000).	
	104	Ninan et al. Tetrahedron., 48:6709:16 (1992).	
	105	OLSZEWSKI, et al. Evidence of Interactions Between Melanocortin and Opioid Systems in Regulation of Feeding, Neuroreport, Vol 12, No. 8, June 13, 2001, pages 1727-1730; XP009035026.	
	106	PARR et al. J. Immunol., 169:856-864 (2002)	
	107	PASTERNAK et al. J. of Med. Chem., 23:674-676 (1980)	
	108	PAVULURI, et al., "Topiramate Plus Risperidone for Controlling Weight Gain and Symptoms in Preschool Mania, Journal of Child and Adolescent Psychopharmacology vol. 12 Number 3, 2002. p. 271-273	
	109	PORTOGHESE et al. Life Sci., 31:1283-1286 (1982).	

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	110	PORTOGHESE et al. J. Med. Chem., 29:1855-1861 (1986).	
	111	PORTOGHESE et al. J. Med. Chem., 29:1650-1653 (1986).	
	112	PORTOGHESE, P.S. J. Med. Chem., 35:1927 (1992).	
	113	POTTER, et al. "Sustained Weight Loss Associated with 12-month topiramate Therapy" Epilepsia, Raven Press Ltd. New York, vol 38, No. Suppl 8, 1997, Page 97	
	114	Remington's Pharmaceutical Sciences. 18th Edition; Easton, PA: Mack Publishing Co. (1990).	
	115	ROWLAND, et al. "Psychopharmacology, 159:111-116(2001)	
	116	Sackellares et al. Epilepsia; 26(3):206-211 (1985).	
	117	SASHIWA et al. Macromolecules, 33:6913 (2000).	
	118	SAPER et al. "The need to feed: Homeostatic and hedonic control of eating," Neuron, 36:199-211 (2002).	
	119	SAYRE et al. J. Med. Chem., 27:1325 (1984).	
	120	SCHMIDHAMMER et al. A. Helv. Chim. Acta, 77:999 (1994)	
	121	Schmidt et al. Epilepsy Research; 15:67-73 (1993).	
	122	Shapiro et al. "Additive Benefits of Combination Therapy with Sibutramine and Rimonabant on Body Weight, Insulin Sensitivity and Lipoproteins in Diet-Induced Obese Mice," 2005 NAASO Annual Meeting, Poster 405-P	
	123	Shapira et al. "Treatment of Binge-Eating Disorder with Topiramate: A Clinical Case Series." J. Clin. Psychiatry; 61(5):368-371 (2000).	
	124	SHELTON, Richard C., "Classification of Antidepressants and their Clinical Implications" Primary Care Companion J. Clin. Psychiatry 2003-5 (Supp. 7) pp. 27-32	
	125	SPIGSET, et al. Therapeutic Approaches to Bulimia Nervosa, Expert Opinion on Therapeutic Patents, Vol. 11, No. 3, 2001, Pages 463-477; XP002292382	
	126	STEPINSKI et al. Internat. J. of Peptide & Protein Res., 38:588-592 (1991).	
	127	TAMIZ et al. J. Am. Chem. Soc., 122:5393-5394 (2000).	
	128	TAMIZ et al. J. Med. Chem., 44:1615:1622 (2001).	

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	129	THEARLE, et al. "Obesity and Pharmacology" Endocrinology and Metabolism Clinics of North American" W.B. Saunders Company, Philadelphia US Vol 32, No. 4, pp. 1005-1024. (2003)	
	130	Wadden et al. "Effects of Sibutramine Plus Orlistat in Obese Women Following 1 Year of Treatment by Sibutramine Alone: A Placebo-Controlled Trial," Obesity Research; 8(6):431 (2000).	
	131	WANG, et al., "Gabapentin augmentation therapy in bipolar depression" Bipolar Disorders 2002, 4; 296-301.	
	132	WERNEKE, et al. Options for Pharmacological Management of Obesity in patients Treated with Atypical Antipsychotics, International Clinical Psychopharmacology, Vol 17 No. 4, 2002, pages 145-160; XP009035036	
	133	Wilding. Current Drug Targets; 5:325-332 (2004).	
	134	ZENG, et al. "Tetrahedron Lett. 29:5123 (1988)	
	135	ZHANG, et al. "Positional Cloning of the Mouse obese gen and its humane homologue" Nature 372:425-432 (1994)	
	136	ZHU, et al. Pharmacologic Treatment of Eating Disorders, Canadian Journal of Psychiatry, Vol 47 No. 3, April 3, 2002 pages 227-234; XP009035028	
	137	International Search Report PCT/US03/15703	

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